Improved Outcomes in Pediatric Sepsis-Associated (SA) AKI: Comparison of the Selective Cytopheretic Device for Pediatrics (SCD-PED) Surveillance Registry (SAVE) with a Historical Cohort

QUELIMMUNE (SCD-PED)
PediAtric SurVeillance REgistry

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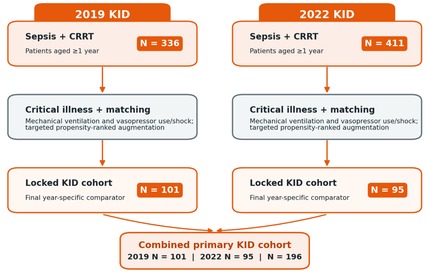
Background

- SCD-PED is approved under an FDA humanitarian device exemption (HDE) for patients ≥10 kg and ≤22 years with sepsis-associated acute kidney injury (AKI) requiring renal replacement therapy (RRT)
- The FDA mandated SCD-PED post-approval registry (SAVE) enrolled 50 clinically complex patients, including substantial extracorporeal membrane oxygenation (ECMO) use[1]
- We compared survival in SCD-PED–treated patients with two clinically aligned, covariate balanced external cohorts from KID, a large US pediatric inpatient database representing broad clinical complexity, including ECMO[2]

Methods

- **Design:** Exploratory observational external-control cohort study comparing 50 SAVE + 1 non-registry case* vs. KID 2019 and 2022 (**see below**)
- **Cohorts:** Eligible KID cases: age ≥1 y with sepsis, continuous RRT (CRRT), invasive mechanical ventilation (IMV), and vasopressor (VP) use or shock; Two SCD-PED analytic cohorts: Primary (>1 day of SCD-PED therapy to allow for sufficient treatment exposure) and Landmark sensitivity (survival beyond 1 day post-initiation); the KID landmark was approximated by survival beyond the calendar day of CRRT initiation
- **Survival endpoints:** Day-90 (**Primary**); Days 28, 60, and hospital discharge (Supportive); Day-90 time-to-death
- **Analysis:** Frequentist methods reported odds ratios (OR) with 95% CIs. Bayesian: estimated risk differences and the probability of higher SCD-PED survival, with >95% representing complementary evidence
- **SAVE only outcomes:** New bloodstream infections ≤28 d of SCD-PED initiation, device-related adverse events (AEs), and Day-90 RRT-free status among survivors not RRT-dependent at baseline descriptively reported

Results – KID Cohort Derivation



Highly clinically complex, critically ill patients across all analytic cohorts

- 100% CRRT in both cohorts; >95% IMV and VP use/shock in both cohorts
- ECMO: 33% to 34% in SAVE and 28% to 29% in KID
- Substantial malignancy, immunocompromised, hemophagocytic lymphohistiocytosis (HLH), and transplant-related complexity
- Other characteristics were similar except for age (KID patients had a higher mean age)

*One previously reported non-registry SCD-PED patient was included for consistency with prior analyses; treatment details were obtained from the published case report[3]

Results – Day-90 Survival Higher With SCD-PED in Primary and Landmark Analyses

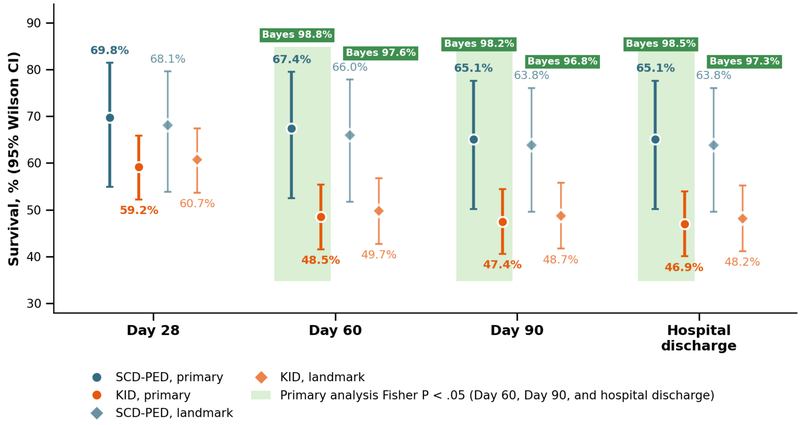
COHORTS		OBSERVED SURVIVAL	FREQUENTIST	BAYESIAN
PRIMARY EXPOSURE-DEFINED ANALYSIS				
SCD-PED: 42 registry + 1 nonregistry, N = 43	vs Combined primary KID cohort, N = 196	SCD-PED 65.1% KID 47.4% +17.7 pp	OR 2.07, 95% CI, 1.04-4.11, Fisher P = .043	P(benefit) 98.2%, 95% CrI, +1.0 to +32.0, Posterior RD +17.0 pp
LANDMARK SENSITIVITY ANALYSIS				
SCD-PED: 46 registry + 1 nonregistry, N = 47	vs Combined landmark KID cohort, N = 191	SCD-PED 63.8% KID 48.7% +15.1 pp	OR 1.86, 95% CI, 0.96-3.60, Fisher P = .074	P(benefit) 96.8%, 95% CrI, -0.9 to +29.3, Posterior RD +14.6 pp

For the primary SAVE cohort, 8 patients were excluded because they received ≤1 day of SCD-PED therapy.

For the landmark SAVE cohort, 4 patients were excluded because they died <1 day of SCD-PED initiation.
For the landmark KID cohort, hospitalizations ending in death on the calendar day of CRRT initiation were excluded.

SAVE was associated with a higher Day-90 survival versus combined KID in the primary analysis, with directionally higher survival in the landmark cohort analysis.

Results – Survival Favored SCD-PED at Every Time Point in Both Analyses



Day-60, Day-90, and in-hospital survival met the frequentist threshold in the primary analysis and exceeded the 95% Bayesian threshold in both analyses.

Results – Year-Specific Comparisons and Day-90 Mortality Models Consistently Favored SCD-PED

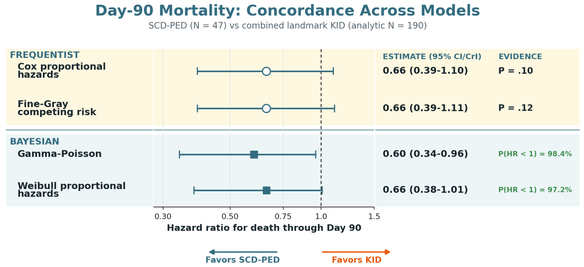
	KID 2019	KID 2022	Combined KID
Day 28	91.4% +11.6 pp	83.0% +8.1 pp	89.5% +9.8 pp
Day 60	98.9% +20.1 pp	96.9% +16.2 pp	98.8% +18.3 pp
Day 90	98.8% +19.9 pp	94.3% +14.0 pp	98.2% +17.0 pp
Hospital discharge	98.8% +19.9 pp	95.4% +15.0 pp	98.5% +17.5 pp

70% to <80% | 80% to <90% | 90% to 95% | >95% Bayesian threshold | Fisher P < .05

Cells show posterior probability and posterior mean absolute survival difference (SCD-PED - KID).

Posterior mean survival differences favored SCD-PED in all 12 comparisons; 8 exceeded the predefined 95% threshold.

All 4 Day-90 mortality models favored SCD-PED (HR range, 0.60-0.66); both Bayesian models exceeded 95%.



Results (SAVE Registry Only) – No Device-Related Infections or AEs

- No device-related adverse events (AEs) occurred
- Secondary BSIs occurred in 12% of patients within 28 days of SCD-PED initiation, including 6% during treatment; all were adjudicated by an independent data and safety monitoring board (DSMB) to be unrelated to device
- Twenty (83%) of the 24 survivors who were not RRT-dependent at baseline were independent of RRT at Day 90

Conclusions

- **Survival consistently favored SCD-PED across all endpoints, analytic cohorts, and complementary analytic approaches**
- **In the primary exposure-defined analysis, Day-90 survival was significantly higher with SCD-PED (P = 0.043) while the landmark sensitivity analysis was directionally consistent. Bayesian probability of Day-90 survival benefit exceeded the predefined 95% threshold in both analyses (98.2% and 96.8%)**
- **These findings provide supportive post-approval evidence of favorable safety and survival associated with real-world SCD-PED HDE use; interpretation is limited by the small sample, nonrandomized external controls, residual confounding, and differing mortality ascertainment**

References:
1.Goldstein SL, et al. *Pediatric Nephrology*. 2026. https://doi.org/10.1007/s00467-026-07181-1. 2. HCUP Kids' Inpatient Database (KID). Healthcare Cost and Utilization Project (HCUP). 2019 and 2022. Accessed July 16, 2026, https://hcup-us.ahrq.gov/kidoverview.jsp. 3. Humes HD, et al. *Pediatric Nephrology*. 2025. https://doi.org/10.1007/s00467-025-06798-y.

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